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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,685	02/25/2002	Martin P. Redmon	0701100e	4621

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EXAMINER	
TRAVERS, RUSSELL S	
ART UNIT	**PAPER NUMBER**
1617	6

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/082,685	Redmon et al
Examiner	**Art Unit**
R.S. Travers J.D., Ph.D.	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 11, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *41-60* is/are pending in the application.

4a) Of the above, claim(s) *46-48, 52-54, and 58-60* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *41-45, 49-51, and 55-57* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The response filed September 11, 2003 has been received and entered into the file.

Claims 41-60 are presented for examination.

Applicant's election with traverse of group I, claims 41-44, 49-50 and 55-56 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that no undue burden would be placed on Examiner. This is not found persuasive because to search distinct inventions, and set forth separate and distinct rejections for all inventions would place an undue burden on Examiner. Examiner will examine groups I and II. The restriction requirement with regard to these two groups is hereby withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 46-48, 52-55 and 58-60 reading on non-elected subject matter are hereby withdrawn from consideration.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude

patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 41-45, 49-51 and 55-57 are rejected under 35 U.S.C. § 103 as being unpatentable over Villani et al and Aberg et al, in view of Blaug et al, Hartauer et al, Handbook of Pharmaceutical excipients and Remington's Pharmaceutical Sciences all of record.

Villani et al and Aberg et al teach descarboethoxyloratadine ((997) column 10), ((716) column 21) and analgesic compounds ((997) column 7, lines 15-21) as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating inflammation, viewed by the skilled artisan as immuno-suppressive, and differing from those active ingredients taught in the prior art, not at all. Claims 41-45, 49-51 and 55-57, and the primary references, differ as to:

1) the recitation of lactose, or sugars as reactive to the active ingredient,

2) recitation of a pill free of lactose, or sugars, and

3) recitation of a coating.

Blaug et al, Hartauer et al, and Handbook of Pharmaceutical excipients teach various amine compounds, in high temperature and humidity situations reacting with various sugars, producing a concomitant reduction in active ingredient levels. The

skilled artisan possessing these teachings would have been motivated to eliminate lactose and sugars from those medicaments containing amine active ingredients, such as those herein claimed. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-inflammatory agents, analgesic and decongestant active ingredients, excipients and carriers. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Applicants' claims specifically require lactose free, anhydrous and pill formulations, although not a reciting compositions requiring all three limitations. The skilled artisan would have seen anhydrous pill formulations, free of lactose, and the administration of these medicaments as residing in the skilled artisan purview. Additionally, the skilled artisan, possessing the Blaug et al, Hartauer et al, and Handbook of Pharmaceutical excipients teachings regarding various amine compounds propensity to, in high temperature and humidity situations, to react with various sugars, producing a concomitant reduction in active ingredient levels would have seen as obvious the elimination of sugars concomitantly with maintaining minimal hydration. The skilled artisan possessing these teachings would have been motivated to eliminate lactose and sugars from those medicaments containing amine active ingredients, while maintaining anhydrous conditions, such as those herein claimed.

Claims 41-45, 49-51 and 55-57 require coating the dosage form with an inert coating agent. Remington's Pharmaceutical Sciences teaches pharmaceutical medicament coatings as an old and well known pharmaceutical practice. These methods are employed for manifold uses by the Pharmaceutical practitioner. To employ one, or another conventional coating method residing in the purview of the skilled artisan would have been seen as the selection from among obvious alternatives.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617